

510 (k) Summary**MAY 02 2013****1. Submitter Information**

Company name Biotest Medical Corporation

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Date Prepared May 2nd, 2013

2. Name of Device

Trade/Proprietary Name Smartest™ Glucowise Blood Glucose Monitoring System, Model 6267-S

 Smartest™ Glucowise MULTI Blood Glucose Monitoring System, Model 6267-M

Common Names *In Vitro* Diagnostic Glucose Test System

Product Code NBW, System, Test, Blood Glucose, Over-the-Counter

 CGA, Glucose Oxidase, Glucose

 JJX, Single (Specified) Analyte Controls

Classification Panel Clinical Chemistry

Device Class Class II

C.F.R. Section 862.1345

3. Predicate Device

Trade/Proprietary	Name Smartest™ SuperCheck 1 Blood Glucose Monitoring System, (Model 6268)
Common/Usual Name	<i>In Vitro</i> Diagnostic Glucose Test System
Submitter	Biotest Medical Corporation
510 (k) Number	K091815

4. Device Description

The Smartest™ Glucowise Blood Glucose Monitoring System (Model 6267-S, 6267-M) is a product kit consisting of a blood glucose meter, test strips, control solutions, a lancing device, lancets, and instructions for use. The data download functionality is optionally available and sold separately.

To perform a test, a glucose test strip is inserted into the top of the device. When a small drop of blood is applied to the end of the test strip, glucose reacts with the reagents on the test strip, producing an electrical current that is proportional to the blood glucose concentration. The glucose concentration is calculated by the glucose meter and is based on the electrical current measured.

The quantitative glucose concentration (in mg/dL or mmol/L) is displayed on the display screen.

5. Intended Use/Indications for Use

The Smartest™ Glucowise Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.

It is not intended for the diagnosis or screening for diabetes mellitus.

The Smartest™ Glucowise Blood Glucose Monitoring System has the same intended use as previously cleared for the Smartest™ SuperCheck 1 Blood Glucose Monitoring System (K091815).

The Smartest™ Glucowise Blood Glucose Monitoring System has done a cleaning and disinfection validation test to comply with “Letter to Manufacturers of Blood Glucose Monitoring Systems Listed with the FDA” dated September, 30th, 2010.

For single patient use

Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S

The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm. The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S is intended to be used by a single person and should not be shared.

The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Smartest™ Glucowise Test Strips are for use with the Smartest™ Glucowise Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm.

The Smartest™ Glucowise Control Solutions are for use with the Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S as a quality control check to verify that the meter and test strips are working together properly.

For multiple patient use

Smartest™ Glucowise MULTI Blood Glucose Monitoring System, Model 6267-M

The Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm. The Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancets.

The Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should

be done only during steady - state times (when glucose is not changing rapidly).

The Smartest™ Glucowise MULTI Test Strips are for use with the Smartest™ Glucowise MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm.

The Smartest™ Glucowise MULTI Control Solutions are for use with the Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M as a quality control check to verify that the meter and test strips are working together properly.

6. Comparison to Predicate Device

For the proposed Smartest™ Glucowise device, the modification from the cleared Smartest™ SuperCheck 1 (K091815) is the removal of talking feature.

- **Voice feature change from talking to non-talking**

This modification involves the removal of speaker component as well as talking software module from Smartest™ SuperCheck 1 (Model 6268). This modification was made due to customer's input and marketing consideration. Smartest™ Glucowise Blood Glucose Monitoring System (Model 6267-S, 6267-M), in all functions and specifications are exactly same as Smartest™ SuperCheck 1 (Model 6268) except for the talking feature. The modification in talking feature will not affect the intended use of the device, and it will not significantly affect safety or effectiveness.

The modification maintain the integrity of the Smartest Glucowise device (Model 6267-S, 6267-M) as described in the original clearance in terms of the intended use of the device (i.e., the quantitative measurement of glucose in capillary blood), and the fundamental scientific technology employed.

The predicate device and candidate device have same appearance. Product sterilization, shelf-life, and biocompatibility are unaffected by the modifications and are equivalent to the legally marketed Smartest™ SuperCheck 1 (K091815).

For the reasons outlined above, the Smartest Glucowise device (Model 6267-S, 6267-M) is eligible for Special 510(k) in accordance with FDA guidance.¹

¹ Center for Devices and Radiological Health. *The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance*. March 20, 1998.

7. Performance Studies

Biotest Medical Corp. has conducted a risk analysis and has performed the necessary verification and validation activities to demonstrate that the design outputs of the modified device, Smartest™ Glucowise Blood Glucose Monitoring System (Model 6267-S, 6267-M), meet the design input requirements.

8. Conclusion

Modifications to the cleared device, Smartest™ SuperCheck 1 (K091815), include voice feature change from talking to non-talking. The modifications maintain the integrity of the Smartest™ SuperCheck 1 (K091815) as described in the original clearance in terms of the intended use of the device (i.e., the quantitative measurement of glucose in capillary blood), and the fundamental scientific technology employed. For the reasons outlined above, the Smartest™ Glucowise Blood Glucose Monitoring System (Model 6267-S, 6267-M) is eligible for Special 510(k) in accordance with FDA guidance.

In summary, the Smartest™ Glucowise Blood Glucose Monitoring System (Model 6267-S, 6267-M) described in this submission is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

Biotest Medical Corporation
C/O Ms. Amanda Chiang
NO.3 - 2 CHIEN-KUO ROAD, TEPZ TANTZU
TAICHUNG, TAIWAN 42760 TW

Re: K122525

Trade/Device Name: Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S

Smartest™ Glucowise MULTI Blood Glucose Monitoring System, Model 6267-M

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product Code: NBW, CGA, JJX

Dated: April 03, 2013

Received: April 04, 2013

Dear Ms. Chiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k122525

Device Name: Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S

Indications for Use:

The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm. The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S is intended to be used by a single person and should not be shared.

The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Smartest™ Glucowise Test Strips are for use with the Smartest™ Glucowise Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm.

The Smartest™ Glucowise Control Solutions are for use with the Smartest™ Glucowise Blood Glucose Monitoring System Model 6267-S as a quality control check to verify that the meter and test strips are working together properly.

Prescription Use _____

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use x _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k122525

Indications for Use Form

510(k) Number (if known): k122525

Device Name: Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M

Indications for Use:

The Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm. The Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancets.

The Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Smartest™ Glucowise MULTI Test Strips are for use with the Smartest™ Glucowise MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or forearm.

The Smartest™ Glucowise MULTI Control Solutions are for use with the Smartest™ Glucowise MULTI Blood Glucose Monitoring System Model 6267-M as a quality control check to verify that the meter and test strips are working together properly.

Prescription Use x

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use x

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k122525